REMARKS / ARGUMENTS

The action by the Examiner of this application, together with the cited references, has been given careful consideration. Following such consideration, claims 1, 4, 7, 9, 10 and 11 have been amended to define more clearly the patentable invention applicant believes is disclosed herein. Claim 2 has been canceled. Claims 3, 5, 6, 8, 12 - 22 are unchanged by the present amendment paper. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

The Examiner rejected claims 2, 4, 7 and 10-11, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Appropriate corrections have been made by amendment. Accordingly, it is respectfully requested that the Examiner now withdraw the 35 U.S.C. 112, second paragraph rejection.

The present invention is directed to a fluid over-flow/make-up air assembly for use with a processing system for sterilizing or microbially deactivating instruments and devices. The fluid over-flow/make-up air assembly includes a manifold, an overflow port, an overflow valve assembly and a filter assembly. The manifold has an interior cavity that is in fluid communication with the processing chamber of the processing system. The manifold is located above the processing chamber to insure that all air is removed from the processing system during filling of the processing system. An overflow port in the manifold allows for air removal from the processing chamber. The overflow port is positioned at the top of the cavity in the manifold to facilitate the removal of air from the manifold's cavity. Located within the overflow port is an overflow valve assembly. The overflow valve assembly includes a check valve that allows fluid

to exit the manifold, but not enter. The overflow valve has two positions. In a first position, the overflow valve is seated in the overflow port and fluid is not able to enter or exit the manifold. When the pressure inside the manifold is greater than that on the outside of the manifold, the overflow valve moves to a second position. In this second position, the overflow valve allows fluid to exit the cavity in the manifold. The overflow valve assembly is positioned at the top of the cavity in the manifold to aid in the removal of air from the processing chamber. In this respect air may be created during the operation of the processing system by the chemical reaction occurring in the processing chamber. The cavity in the manifold allows the air in the processing chamber to collect in the manifold's cavity and not in processing chamber and to be removed from the processing system through the overflow valve assembly. Excess air in the processing chamber might result in incomplete microbial deactivation of the instruments and devices in the processing chamber.

The over-flow/make-up air assembly also includes a filter assembly. The filter assembly is comprised of a filter membrane, filter valve assembly, a passage connecting the filter membrane to the filter valve assembly and a mounting portion. The filter valve assembly is oriented so that the valve actuates when there is a difference in pressure between the cavity in the manifold and the external surroundings of the filter assembly. The filter valve assembly has two positions, i.e. a closed position and an open position. In the closed position, the filter valve assembly prevents fluid or air in the manifold chamber from flowing into the filter assembly. This position protects the filter membrane from contact with any liquid or contaminated air within the chamber. If liquid contacts the filter membrane, it becomes an ineffective barrier to harmful microorganisms.

When the pressure on the face of the valve is less than the pressure in the passage of the filter assembly, the filter valve moves to the open position. In this open position, the filter valve assembly allows air to pass through the filter membrane, through the connecting passage and enter the chamber through the filter valve assembly. The mounting portion of the filter assembly attaches the filter assembly to the manifold of the fluid over-flow/make-up air assembly. The mounting portion allows the filter assembly to be quickly secured or released from the manifold of the fluid over-flow/make-up air assembly while maintaining the passage in the filter assembly sterile.

At the beginning of an operating cycle, the processing system fills with either water or the microbial deactivation fluid. Once the level of the fluid reaches the top of the processing chamber, the fluid flows into the cavity in the fluid over-flow/make-up air manifold. As the fluid fills the pressure inside the manifold cavity becomes greater than the pressure on the outside of the manifold. Once a predetermined pressure is met, the overflow valve assembly moves to the open position and allows the fluid to exit. As the fluid or microbial deactivation fluid fills the manifold, the surface of the filter valve assembly facing the chamber is exposed to the microbial deactivating fluid.

At the end of the processing cycle, the chamber is drained of all fluid and microbial deactivation fluid. During draining, the pressure inside the chamber drops below the pressure in the surrounding environment. At this point the filter valve assembly moves to the open position and air enters the manifold chamber through the filter assembly. It can be appreciated that because the filter membrane is made of a bacteria-retentive material no microorganisms are able to pass through the filter membrane. The passage between the filter membrane and the

processing chamber remains sterile because the passage between the filter membrane and the filter valve assembly has been pre-sterilized. The passage from the filter membrane to the processing chamber remains sterile because the filter valve assembly is permanently connected to the filter membrane. Applicant respectfully submits that none of the cited references above or together teaches, suggests or shows the invention as presently claimed.

Based on the Examiner's comments, claim 9 has been amended to include the limitations of claims 1 and 8. It is believed that claim 9 is now allowable.

Claim 1 has been amended to indicate that the filter assembly includes an interior passage and a filter membrane, and that a portion of the filter valve assembly is exposed to the passage of the filter assembly and another portion of the valve assembly is exposed to the cavity. Claim 1 was further amended to indicate that the filter assembly is sterile from the filter membrane to the filter valve assembly.

The Examiner rejected claims 11-12 and 15-16 under 35 U.S.C. 102(b), as being anticipated by U.S. Patent No. 4,533,068 to Meierhoefer. In addition, the Examiner has rejected claims 11-12, 15-16 and 120 as being anticipated by U.S. Patent 4,731,222 to Kralovic et al. Furthermore, the Examiner has rejected claims 11-18 as being anticipated by U.S. Patent 5,928,516 to Hopkins et al. The Examiner has also rejected claims 11-12, 15-16 and 19-20 as being anticipated by U.S. Patent 5,217,698 to Siegel et al.

It is respectfully submitted that none of the cited references, taken individually or in combination, teaches or suggests the applicants' invention as defined by the present claims.

The Examiner takes the position that Meierhoefer "teaches a sterile solution delivery device constructed having a filter canister connected to a fluid passage and with a filter assembly

containing a bacterial-retentive filter and valve means allowing for air flow in only one direction, the entire assembly being sterile. See column 4, lines 40-68, column 5, lines 10-15 and lines 30-60, column 7, lines 25-30 and lines 45 –50."

With reference to column 4, lines 23 – 29, Meierhoefer teaches that "a check valve 28 is *secured inwardly of the spout 20* in known manner to permit the passage of sterile solution (not shown) therethrough when the compressible container 14 is squeezed or otherwise compressed to express sterile solution *from the container*." Referring also to column 4, lines 52-59, Meierhoefer teaches that "the inward terminus 50 of the *air inlet port 18* can be provided with an interior cylindrical housing or seat 30 *upon which is secured a filter 52* which comprises generally a filter housing 34, a hydrophobic membrane 32 and a suitable attaching collar or clip 36, which clip functions to *secure the filter 52 upon the inner terminus of the seat 30.*" In other words, Meierhoefer teaches a device wherein the filter is located on the air inlet port 18, while the check valve is located on the spout to allow the sterile solution to exit the container.

In contrast to Meierhoefer, the claimed device places a filter valve assembly between the filter membrane and the cavity of the manifold. The filter valve assembly and the filter membrane are connected by a single air passage. The filter valve assembly prevents the filter membrane from coming in contact with liquid that may be in the cavity of the manifold. Meierhoefer does not teach such a structure or how to prevent the fluid from coming in contact with the filter membrane. Further, Meierhoefer does not teach an integral filter assembly where a sterile passage exists between a filter membrane and a filter valve assembly.

The Examiner also takes the position that Kralovic et al., teaches "an air inlet assembly 80 selectively interconnectable with an automated liquid sterilization system, which selectively

interconnects the interior of a reservoir with a source of sterile air. Within the valve passage is a sterilizing filter that removes bacteria. See column 6, lines 34-40 and lines 54, 56, and Fig. 1."

With reference to column 6, lines 34-40, Kralovic et al. teaches that air inlet valve 80 connects reservoir 30 with an air sterilizing means 82. Kralovic et al. thus teaches an air inlet valve in the passage between the air sterilizing means and the reservoir. Kralovic et al. also teaches that air inlet valve 80 is opened during the draining of the reservoir. Kralovic et al. shows a valve that is opened when provided with a signal from a control system.

In contrast to Kralovic et al., the claimed invention defines an integral filter assembly wherein a filter membrane is permanently connected to a filter valve assembly by a single passage. The filter valve assembly and the filter membrane are permanently attached to each other to maintain the sterility of the passage between the filter membrane and the filter valve assembly. The claimed invention also defines a filter valve assembly that opens due to a pressure difference that exists between the environment and the manifold cavity. The filter valve assembly uses a spring-loaded mechanism to keep the valve closed until a predetermined pressure difference is achieved. Actuation of the filter valve assembly is not controlled by a signal from the system controller, as in the Kralovic et al. reference.

The Examiner also takes the position that Hopkins et al. teaches "filter assembly containing a bacterial-retentive filter effective to 0.02 microns made of PTFE within a sterile canister intended for installation on a housing. See column 5, lines 1-5, column 7, lines 40-54, and column 8, lines 1-15."

Hopkins et al., teaches that a bacterial-retentive filter membrane is attached to a housing. The membrane can be part of a housing that permanently or detachably connects to a housing.

In contrast to Hopkins et al., a filter assembly according to the present invention incorporates a bacterial-retentive filter together with a filter valve assembly. The filter valve assembly keeps fluid from the membrane. The claims also define a sterile passage between the filter membrane and the filter valve assembly. The filter membrane and the filter valve assembly form one assembly that is detachable from the over-flow/make-up air assembly.

With respect to the Siegel et al. reference, the Examiner further takes the position that Siegel et al. teaches "an air inlet valve assembly selectively inter-connectable with an automated liquid sterilization system, which selectively interconnects the interior of a reservoir with a source of sterile air. Within the valve passage is a sterilizing filter that removes bacteria. See column 6, lines 53-63."

Siegel et al. teaches a similar configuration as Kralovic et al., except in the Siegel et al. reference the air inlet valve is replaced with a check valve. The check valve in Siegel et al. is only open when a difference in pressure between the chamber and the surroundings is achieved.

In contrast to Siegel et al., the present claims define a structure that is comprised of a permanent connection between the filter valve assembly and filter membrane. Siegel et al. does not teach, suggest or show a structure that has a replaceable, integral filter assembly that is comprised of an air inlet, an air outlet, an air passage extending between the air inlet and air outlet, a filter medium disposed within the air passage between the air inlet and air outlet, a directional valve assembly disposed within the passage between the filter medium and the air outlet for regulating the flow of air through the passage, wherein the directional valve permits air flow only in a direction from the air inlet to the air outlet, wherein the air passage between the filter medium and the directional valve assembly is sterile or microbially deactivated, and that

has a mounting portion for attachment of the filter assembly in its entirety to a sterilization or microbial deactivation system. The mounting portion also provides a means to quickly secure and release the filter assembly from the sterilization or microbial deactivation system while maintaining the fluid passage in the filter assembly sterile as stated in claims 11 and 15.

The Examiner also rejected claims 13-14, 17-18 and 21-22 under 35 U.S.C. 103(a) as being unpatentable over Siegel et al. and claims 11-12, 15-16 and 19-20 under 35 U.S.C. 103(a) in view of Hopkins et al. It is respectfully submitted that none of the cited references, taken individually or in combination, teaches, suggests or shows the applicants' invention as set forth in the above stated claims.

The Examiner also rejected claims 1-8 and 10 as being unpatentable over Siegel et al., together with Meierhoefer. The Examiner takes the position that Siegel et al. additionally teaches an automated liquid sterilization system that is modular and has operating parameters that are sensed and controlled. The Examiner takes the position that Siegel et al. can be combined with Meierhoefer thus making claims 1-8 and 10 unpatentable.

It is respectfully submitted that one of ordinary skill in the art would not consider combining the automated liquid sterilization system of Siegel et al. with a sterile solution delivery and venting device used on a container, as taught by Meierhoefer. Furthermore, neither Siegel et al. nor Meierhoefer, taken individually or in combination, overcomes the deficiencies mentioned above with respect to the Siegel et al. reference. For example, such a combination would not teach, suggest or show a filter assembly comprised of a filter valve assembly, an interior passage and a filter membrane wherein a portion of the filter valve assembly is exposed to the passage of the filter assembly and another portion of the valve assembly is exposed to the

manifold's cavity. Further, the combination does not teach, suggest or show a filter assembly having a sterile passage from the membrane to the filter valve assembly.

The cited references made of record and not relied upon have been noted.

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters that need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: April 28, 2005

Christine Goellner